DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Alliance Medical Corporation
c/o Ms. Moira Barton
Regulatory Affairs Manager
10232 South 51st Street
Phoenix, AZ 85044

NOV 1 2004

Re: K030279 - Supplemental Validation Submission
Trade Name: See Enclosed List
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter and Patient Transducer and Electrode Cable (including connector)
Regulatory Class: Class II (two)
Product Code: NLH & DSA
Dated: January 24, 2003
Received: January 27, 2003

Dear Ms. Barton:

The above-referenced premarket notification (510(k)) was cleared by the Office of Device Evaluation (ODE) on October 3, 2003. We have received your supplemental validation data as required for reprocessed single-use devices by the Medical Device User Fee and Modernization Act of 2002. After reviewing your supplemental validation data, we have determined the devices listed in the enclosure accompanying this letter are substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market these devices, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your devices are classified (see above) into either class II (Special Controls) or class III (PMA) they may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your devices in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your devices comply with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's applicable requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

The FDA finding of substantial equivalence of your devices to legally marketed predicate devices results in classification for your devices and thus, permits you to legally market the devices. This letter will allow you to continue marketing the devices listed in the enclosure accompanying this letter.

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

B Zimmerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

Enclosure – List of Devices

K030279 Models [OEM, (n)] (n = 6)
Medtronic (6)
043302M
043325M
043328M
04401SM
04402SM
072322M

II. Indications for Use Statement

510(k) Number (If known): K030279

Device Name: Alliance Medical Corporation Reprocessed Electrophysiology (EP) Catheters

Indications for Use: Reprocessed Electrophysiology (EP) Catheters are indicated for temporary intracardiac sensing, recording, stimulation and electrophysiological mapping of cardiac structures.

Indications for Use: Reprocessed electrophysiology catheter cables are indicated for use with the appropriate electrode catheter during electrophysiology studies.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K030279

Prescription Use X
(per 21 CFR 801.109)

or

Over-the-Counter Use ____

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OCT 03 2003

ALLIANCE
MEDICAL CORPORATION

PART B: 510(k) SUMMARY

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(480) 763-5300 (o)
(480) 763-5310 (f)

Date of preparation: 6/13/2002

Name of device: *Trade/Proprietary Name:* Reprocessed Electrophysiology Catheter
Common or Usual Name: Electrophysiology Catheter or Electrode Recording Catheter
Classification Name: Electrode Recording Catheter

Predicate device(s): Legally marketed Electrophysiology Catheter devices under various 510(k) premarket notifications.

K931794	Marinr Series EP Diagnostic Catheters
K951347	Marinr Series EP Diagnostic Catheters
K981642	Stablemapr Steerable Intracardiac Catheters

Device description: Diagnostic electrophysiology (EP) catheters are specially designed electrode catheters that transmit electrical impulses and can be positioned for endocardial recording or stimulation. Diagnostic EP catheters incorporate a handpiece, a flexible shaft and a distal tip section containing diagnostic electrodes. The distal tips of deflectable catheters can be deflected into a curve by manipulating the handpiece; fixed curve catheters have an established distal tip shape.

Intended use: Reprocessed Electrophysiology Catheters are intended for temporary intracardiac sensing, recording, stimulation, and electrophysiological mapping of cardiac structures.

Indications statement: Reprocessed diagnostic EP catheters are indicated for temporary intracardiac sensing, recording, stimulation and electrophysiological mapping of cardiac structures.

Reprocessed electrophysiology catheter cables are indicated for use with the appropriate electrode catheter during electrophysiology studies.

Technological characteristics:

The design, materials, and intended use of Reprocessed Electrophysiology (EP) Catheters are identical to the predicate devices. The mechanism of action of Reprocessed Electrophysiology (EP) Catheters is identical to the predicate devices in that the same standard mechanical design, materials and sizes are utilized. There are no changes to the claims, intended use, clinical applications, patient population, performance specifications, or method of operation.

Alliance Medical Corporation's reprocessing of electrophysiology catheters includes removal of adherent visible soil and decontamination. Each individual electrophysiology catheter is tested for appropriate function of its components prior to packaging and labeling operations.

Performance data:

Bench and laboratory testing was conducted to demonstrate performance (safety and effectiveness) of the Reprocessed Electrophysiology (EP) Catheters.

- Biocompatibility
- Validation of reprocessing
- Sterilization Validation
- Function test(s)

Performance testing demonstrates that Reprocessed Electrophysiology (EP) Catheters perform as originally intended.

Conclusion:

Alliance Medical Corporation concludes that the modified device the Reprocessed Electrophysiology (EP) Catheter is safe, effective and substantially equivalent to the predicate devices as described herein.